

## REMARKS

This communication is in response to the Non-Final Office Action that issued on August 2, 2011 (the “**Office Action**”). Claims 1 and 3-18 are currently pending. Reference is also made to Applicants’ paper filed on May 16, 2011 (the “**Previous Response**”) in response to the Final Office Action that issued on February 14, 2011 (the “**Previous Office Action**”).

Claims 1 and 3-18 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Publication No. 2003/0141477 by Miller (“**Miller**”). Claims 12-18 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Miller. Applicants respectfully request reconsideration in view of the remarks that follow.

### **Request to Withdraw Finality of Office Action and** **Request to Clarify Grounds of Rejection of Claims 12-18 on 103(a)**

In the Previous Response, Applicants requested that the finality of the Previous Office Action be withdrawn and that the basis of rejection of claims 12-18 under §103(a) be clarified.<sup>1</sup> Applicants note that the Examiner has declined to address either request in the Office Action. With respect to the rejection of claims 12-18 as allegedly obvious over Miller, applicants note that claim 12 is also rejected in the Office Action under §102(b) as allegedly anticipated by Miller. It is expected that the arguments submitted below in reply to the §102(b) rejection of claims 12-18 as well as those offered in reply to the §103(a) rejection of claims will also be fully responsive to the §103(a) rejection of claims 12-18. If this is not the case, the Examiner is urged to contact the undersigned attorney prior to the issuance of the next office action on the merits so that the substance of any unaddressed rejection can be discussed.

---

<sup>1</sup> See Previous Response, pp. 6-7.

**Claim rejections under 35 U.S.C. §102(b)**

Claims 12-18 stand rejected as allegedly anticipated by Miller. The Examiner has maintained this rejection over Applicants' arguments made in the Previous Response that the "valve stem" disclosed in Miller is not a unitary body as required by claim 12, and that a valve-stem would, in any event, be understood by one skilled in the art to be structurally, functionally and patentably distinct from a septum which is a unitary body as is required by claim 12. In view of the maintenance of the rejection, and the Examiner's reiteration of the grounds of rejection set forth in the Previous Office Action in the most recent Office Action, Applicants respectfully reiterate the arguments made in the Previous Response.

Further, Applicants wish to supplement their position, set forth in the Previous Response, that the Examiner's construction of the term "unitary" in the Office Action and the Previous Office Action is in error. That interpretation goes well beyond the "broadest reasonable interpretation consistent with the specification" that is required by the MPEP and the case law.<sup>2</sup> Because this overly-broad interpretation forms the basis of the §102(b) rejection of claims 12-18, Applicants submit that the rejections should be withdrawn, and respectfully request the same.

The septum is described in general terms in the published specification:

[A] septum generally comprises a flexible membrane that overlies the inlet opening and seals it with the material forming the septum being selected for its ability to continue sealing the port even after repeated punctures by a needle. For example, silicone or other elastomeric materials have been used to form such septa.<sup>3</sup>

---

<sup>2</sup> MPEP § 2111. ("During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.'") *See also Phillips v. AWH Corp.* 75 USPQ2d 1321, 1329 (Fed. Cir. 2005) ("the rules of the PTO require that application claims must 'conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.' 37 C.F.R. § 1.75(d)(1).")

<sup>3</sup> Published specification, ¶ [0015].

The use of the term “septum” in the specification, and the subject matter of claims 12-18, make clear that several definitions of the term “unitary” offered by the Examiner in the Office Action and the Previous Office Action are inapposite.<sup>4</sup> Given the subject matter of the application, the term “unitary” cannot reasonably be read to mean any of the following: “serving as a unit, as of measurement, or estimation” or “of or pertaining to a system of government in which the executive, legislative, and judicial powers of each state in a body of states are vested in a central authority.” Further, the Examiner’s reading of the term “unitary” to mean “of or pertaining to a unit or units” or to refer to a “unitary body” renders the term “unitary” superfluous within the claims. Applicants point out that the meaning “of or pertaining to a unit or units” or a “unitary body” is conveyed by the use of the singular articles “a” or “the” before the singular “septum,” throughout claim 12 and its dependent claims. To read “unitary” as meaning the same thing as “a” and “the” is to read “unitary” out of the claims, and is contrary to the requirement that each claim be given its broadest *reasonable* interpretation. Similarly, given the subject matter of claim 12 is the structure, and not the method of manufacture, of the septum, the narrow interpretation of “unitary” to mean “formed in one piece” is not supported by the context of the claim.

Placing these definitions aside, what remains are two closely related definitions of the term “unitary”: (i) “pertaining to, characterized by, or aiming toward unity” and (ii) “the nature of a unit; having the indivisible character of a unit.” Applicants do not concede to (and in fact object to) the Examiner’s use of these dictionary definitions in substitution for the plain meaning term “unitary” as it is evident from the specification and claims, and as that term would be understood by one skilled in the art. However, Applicants respectfully point out, *arguendo*, that

---

<sup>4</sup> See Office Action, p.2; Previous Office Action, pages 2-3.

even if the term “unitary” is given either of these dictionary meanings in claims 12-18, the claims as a whole are not anticipated by Miller.

In the Office Action, the Examiner concedes that the Miller valve stem is divisible, but contends that “this does not negate the position that the Miller septum \* \* \* has the indivisible character of the unit or whole of the septum.”<sup>5</sup> In fact, the teaching in Miller of an apparatus that is “divisible” does negate the position that Miller has “the indivisible character of the unit or whole of the septum.” The Examiner cannot reasonably interpret Miller’s exclusive teaching of an apparatus with a characteristic (in this case, divisibility) to support a reading of Miller as teaching the opposite of that characteristic (namely, indivisibility).

In addition, as Applicants explained in the Previous Response, Miller discloses a valve stem that is neither characterized by nor aiming for unity. To recap: Miller discloses a valve stem that has a “central axial fluid pathway 50 therethrough.”<sup>6</sup> The stem of Miller is “deformable,” and has a circumferential notch on its exterior surface “providing a point of weakness” and permitting the stem to collapse in on itself to form a tube, “thereby providing increased flow volume within the valve stem, wherein the valve stem collapses and folds inward generally about a fulcrum point which is located at an area of minimal wall thickness.”<sup>7</sup> The valve stem also has a slitted wall at one end which is connected to a channel in its center, and the wall is also designed to collapse about said point of weakness so that fluid can flow through the channel in its center. The totality of the disclosure in Miller makes clear that, if the device were genuinely unitary and by implication indivisible, it would not function as intended. The Miller

---

<sup>5</sup> Office Action, p. 3. (“Again, the fact that it may be ‘divisible’ does not negate the position that the Miller septum is pertaining [sic] to the unit of the septum, is formed as one piece whole, and has the indivisible character of the unit or whole of the septum.”)

<sup>6</sup> See Miller, ¶ [0034]; Figs. 3-7.

<sup>7</sup> *Id.*; Claims 11, 21.

device cannot be unitary, in the sense in which that term is used in the claims of the instant application, because it must be sufficiently non-unitary to cave in on itself to form a channel through which fluid can flow.

Finally, Applicants respectfully reiterate that the Examiner's reading of the term "valve stem" in Miller as synonymous with the term "septum" as it is used in the instant claims is unduly broad, and that one skilled in would understand that the valve stem of Miller is plainly distinct from the septum claimed in the instant application. The distinction is underscored by the description of a septum in the published specification that is reproduced above.<sup>8</sup>

Applicants have previously pointed out that the Examiner's reading of Miller seems to ignore the operative significance of the word "valve" in the term "valve stem."<sup>9</sup> The disclosure of Miller makes clear that the valve stem is designed to close off the valve when not in use but, when compressed by a male connector member, to shift within the valve and permit fluid to flow therethrough.<sup>10</sup> However, the superficial functional similarities between the valve stem of Miller and the septum as claimed in the instant application appear to persuade the Examiner that "the term valve stem is within the broadest reasonable interpretation of the term [septum]" because it "closes off the valve when not in use [and] is similar in function to the Applicants' septum which closes off the orifice when not in use."<sup>11</sup> The Examiner's reliance on a functional analogy to support the assertion that the valve stem disclosed in Miller anticipates the unitary septum claimed herein is contrary to the requirements of the case law and the MPEP.<sup>12</sup> "Even if a prior art device performs all the functions recited in the claim, the prior art cannot anticipate the claim

---

<sup>8</sup> See n. 3, *supra*.

<sup>9</sup> Previous Response, p. 9.

<sup>10</sup> *Id.* at ¶¶ [0037], [0039].

<sup>11</sup> Office Action, p. 3.

<sup>12</sup> MPEP §2114.

if there is any structural difference.” (Emphasis added.) In addition, the functional analogy upon which the Examiner relies in making the rejection does not hold: a valve stem requires only *pressure* to open and permit fluid flow, while the septum requires puncture with a needle. This difference is driven by the facts that the septum resides, when implanted, beneath the skin of a patient, typically in a pocket in the arm or the chest, and it must prevent fluid leakage in a setting where it may be exposed to various pressures simply in the course of a patient’s movement and medical treatments during the course of the day. These functional differences, moreover, are caused by obvious differences in structure such as those set forth above.

“A claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described in a single prior art reference.”<sup>13</sup> Applicants submit, for the foregoing reasons, that Miller fails to describe every element of claim 12 or claims 13-18, which depend from claim 12.

#### **Claim rejections under 35 U.S.C. §103(a)**

Claims 1 and 3-18 stand rejected as allegedly obvious in view of Miller. Applicants believe that the arguments made above in regard to the §102(b) rejection of claims 12-18 fully address the rejection of the same claims on §103(a) grounds as well, and reiterate the arguments made above and those made in the Previous Response. The Applicants’ remarks with respect to the septum recited in the instant claims and the differences between the septum and the valve stem disclosed in Miller are believed to apply, *mutatis mutandis*, to all §103(a) rejections.

In making the §103(a) rejection of claims 1 and 3-11 in the Office Action, the Examiner concedes that Miller does not disclose the limitation of a second opening that is “adapted to

---

<sup>13</sup> See MPEP § 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

connect to a catheter and is substantially perpendicular to the first opening,” but contends that the limitation “would have been an obvious matter of design choice \* \* \* and it appears that the invention would perform equally well with the first and second openings collinear, perpendicular or and any angle to one another.”<sup>14</sup> To the contrary, the published specification explains the necessity of the limitation of perpendicularity between the first and second openings:

Semi-permanently implanted catheters are generally designed to be as small and thin as possible, to simplify the insertion procedure and to reduce discomfort to the patient. Access to such a catheter is typically provided by one or more ports, which are in fluid connection with the catheter and thus with the patient's vascular system. The port or ports generally have a very thin profile, so they may be implanted in the patient with a minimum of discomfort. In most cases, such a port is implanted subcutaneously, in a pocket formed surgically in the patient's chest or arm so that it lies just under the skin, in a location that is easily accessible to medical personnel. More specifically, a septum of the port is positioned just under the skin so that therapeutic agents may be injected into the port through the skin and through the surface of the septum.<sup>15</sup>

One skilled in the art will appreciate that the perpendicular arrangement of the first and second openings, as claimed, promotes apposition of the septum to the skin while reducing thickness and patient discomfort. The needleless valve stem of Miller, by contrast, is designed for use outside of the skin, for example in needleless IV sets.<sup>16</sup> In that setting, the need for compactness that drives the design of ports like the one claimed is essentially absent, so though a variety of angles may be feasible in connectors in an IV set, the 90-degree angle is chosen to solve a particular problem in port design.

“In determining the differences between the prior art and the claims, the question under 35 U.S.C. §103 is \* \* \* whether the claimed invention as a whole would have been obvious.”<sup>17</sup> For the foregoing reasons, Miller fails to render the claimed invention obvious as a whole. Therefore, the Examiner's rejections of Claims 1 and 3-18 on §103(a) grounds are believed to be overcome, and it is respectfully requested that the Examiner withdraw these rejections.

---

<sup>14</sup> Office Action, p.6

<sup>15</sup> Published Specification, ¶ [0002].

<sup>16</sup> See Miller, ¶ [0001]

<sup>17</sup> MPEP § 2141.02.

## CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is respectfully requested.

In the event that there are any questions relating to the application, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (202) 373-6000 so that prosecution of the application may be expedited.

The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4047.

Respectfully submitted,

BINGHAM MCCUTCHEN, LLP

Date: November 7, 2011

By: //Dhruv Kaushal//  
Dhruv Kaushal  
Registration No. 67,340

BINGHAM MCCUTCHEN, LLP  
2020 K Street, NW  
Washington, DC 20006  
Telephone: (202) 373-6000  
Facsimile: (202) 373-6001